biostable polymer mixed with a therapeutic agent."

- Claim 25: sewing ring comprising a "body portion initially formed from a polymer mixed with a therapeutic agent."
- Claim 29: a bioprosthetic heart valve polymer insert containing struts attached to tissue leaflets to form a valve housing, … the polymer insert is initially formed with a releasable therapeutic agent
- Claim 41: annuloplasty ring comprising a body portion. . .initially formed from a biostable polymer mixed with an releasable therapeutic agent;
- Claim 45: a sewing ring comprising a body portion initially formed from a polymer mixed with a therapeutic agent
- Claim 52: prosthetic heart valve comprises a sewing ring comprising a body portion comprising a polymer initially formed with a releasable anti-inflammatory agent
- Claim 56: annuloplasty ring comprises a body portion comprising an biostable polymer initially formed with a releasable anti-inflammatory agent,
- Claim 60: sewing ring . . .forming the annular insert by initially mixing a releasable therapeutic agent with a biocompatible polymer

Support in the specification for requiring a polymer or biostable polymer is initially formed with a therapeutic agent (such as an anti-inflammatory agent) can be found At several places in the specification, including page 15, lines 22-28; page 27, line 22 through page 29, line 15; page 29, line17 through page 30, line 15; page 31, lines 12-29.

Applicants also wish to point out that the independent claims (claims 21, 25, 29, 41, 45, 52, 56, and 62) have been conformed to also require:

- there is a fabric overlayer; and
- the releasable therapeutic agent provides at least one therapeutic effect to the fabric overlayer.

Applicants request entry of the above amendments in order to move forward the selected claims to issuance. As applicants point out in their response, the entered amendments and arguments overcome the present rejections, and respectfully request the present set of claims be allowed to issue.

RESPONSE TO THE EXAMINATION

Applicants response follows the outline of the Examination of mailed 8/14/2002. Each issue raised by the Examiner is inserted prior to applicants response.

1. Rejection of Claim 26 Under 35 USC §112

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1 Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "the metal or metal alloy" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim

Applicants have amended dependent claim 26 to provide antecedent basis from claim 25. Claim 26 has been amended to indicate the heart valve prosthesis for antecedent basis to Claim 25. Additionally dependent claim 26 has been broadened to recite the heart value additionally comprises metal or metal alloy components, thereby removing the limitation that they must be titanium or tantalum.

It is respectfully submitted the provided amendment overcomes the Examiner's rejection under 35 USC § 112 and request the present rejection to Claim 26 be removed.

2. Rejection of Claims 1-4, 9, 10, 12, 14-20 and 73-74 under 35 USC § 102 over Helmus et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 9, 10, 12, 14-20 and 73-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al., 5,447,724

Helmus discloses an implantable medical device, see column 9, lines 52-68, comprising a body portion overlaid by a fabric overlayer, see column 9, lines 38-48, the body portion comprising at least one polymer, intimately mixed with at least one therapeutic agent, see column 9, line 46, wherein the therapeutic agent is capable of being released from the body portion of the device, see column 3, lines 34-47, and column 6, lines 18-25.

As to claim 2, the constituent material comprises at least a polymer, see column 9, line 40.

As to claims 3 and 4, the constituent material comprises a polymer, specifically silicon, see column 2, lines 39-47.

As to claims 9 and 10, the therapeutic agent comprises an anti-inflammatory agent, specifically cortisone, see column 2, line 6.

As to claim 12, the therapeutic agent further comprises an antimicrobial agent, see column 2, line 7.

As to claim 14, the therapeutic agent is coated onto the body portion of the device, see column 4, lines 12-24.

As to claim 15, the therapeutic agent is compounded into the body portion of the device, see column 4, lines 12-24 and column 9, lines 28-49.

As to claim 16, the body portion of the device comprises a liquid core comprising the therapeutic agent, see column 4, lines 12-24 and column 9, lines 38-48.

As to claim 17, the therapeutic agent comprises an antimicrobial agent, see column 2, line 7.

As to claims 18 and 19, the medical device is a prosthetic heart valve, see column 2, lines 66-67

As to claim 20, the fabric overlayer takes the form of a sheath, pouch, an encasement, an enclosure, a layer, a film, or a coating, see column 4, lines 12-24, and column 9, lines 28-49.

As to claims 73-74, an artificial pump is disclosed, see column 9, lines 60-68.

As to claim 20, the fabric overlayer takes the form of a sheath, pouch, an encasement, an enclosure, a layer, a film, or a coating, see column 4, lines 12-24, and column 9, lines 28-49.

As to claims 73-74, an artificial pump is disclosed, see column 9, lines 60-68.

Claims 1-4, 9, 10, 12, 14-20 and 73-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al., US 5,447, 724. The Examiner relies on the teachings of Helmus for as the basis of the present § 102 rejections and in combination with all § 103 rejections.

Applicants have cancelled, without prejudice, all the rejected claims, rendering moot the present rejection. Applicants turning to the Examiner's rejection under § 103.

3. Rejection of Claims 5-8, 21, 22, 24-26, 28-30, 32, 34-39, 41, 42, 44-50, 52, 53, 55-57 under 35 U.S.C. § 103 as unpatentable over Helmus et al. in view of Tweden et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 5-8, 21, 22, 24-26, 28-30, 32, 34-39, 41, 42, 44-50, 52, 53, 55-57, 59-67 and 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,695,419.

Helmus discloses the invention substantially as claimed, see above. Additionally, Helmus discloses that other devices that may be used in the invention include artificial heart components, vascular grafts, heart valves, cardiovascular sutures, etc., see column 9, lines 58-62

However, Helmus does not disclose the fabric overlayer comprising a knitted or woven fabric of polymer fibers, nor does Helmus disclose the polymer comprising polyethyleneterephthalate. Helmus also does not disclose the heart valve prosthesis as comprising a sewing ring, nor an annuloplasty ring.

Tweden discloses a suture/sewing cuff or fabric comprising a knitted or woven fabric of polyester, see column 2, lines 45-50, and see column 3, lines 30-33. Tweden also discloses that for stented bioprosthetic heart valves, the fabric used for the sewing cuff could be coated with a therapeutic agent, see column 2, lines 51-67 It would have been obvious to one of ordinary skill in the art to use the Helmus teachings to provide the therapeutic agent in the knitted or woven fabric polymer fibers on the Tweden heart valve, as a type of medical device specifically disclosed by Helmus that may be coated with a therapeutic agent according to the Helmus invention.

Specifically with respect to claim 8, Tweden discloses that the polymer fibers comprise polyethyleneteraphthalate, see column 5, lines 34-35.

As to claim 21, Tweden discloses a sewing ring (66).

As to claims 22, 30, the polymer insert comprises silicone, see column 3, line 36-38.

As to claims 24, 28, 35, 36, Tweden discloses that the heart valve may be bioprosthetic or mechanical, see column 2, lines 3-6, and lines 30-35.

As to claims 26, 37, 38, 48, 49, 64, 65, the body portion comprises a metal, specifically titanium, see column 3, line 40.

As to claims 29, 60, Tweden discloses that the heart valve comprises a polymer insert containing struts attached to tissue leaflets to form a valve housing, wherein a fabric sheath encloses the polymer insert to form sewing ring, see column 2, line 31

As to claims 41, 56, Tweden discloses an annuloplasty ring (22)

As to claims 71 and 72, the sewing ring constitutes an annular insert.

Claims 5-8, 21, 22, 24-26, 28-30, 32, 34-39, 41, 42, 44-50, 52, 53, 55-57, 59-67, and 69-72 were rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al. 5,895,419.

Helmus is cited for disclosing an implantable medical device having a protective coating applied to the device. This is provided in part by the actual passage cited by the Examiner (column 9, lines 52-68) wherein the Helmus patent teaches to coat those areas of the medical device in contact with the body tissues or fluids. Similarly, the Examiner points out, and as would be consistent with the teaching of Helmus, that Tweden teaches that "the fabric used for the sewing cuff could be coated with a therapeutic agent see column 2, lines 51-67";

Using the teachings of Helmus and the teaching of Tweden, one would coat or impregnate the fabric layer or the device with the therapeutic agent to provide protection of this layer. Using the teachings of Helmus in view of Tweden it would teach away from the design of the device such that the actual component is initially formed from the polymer mixed with the therapeutic agent. Therein, there is no coating of the device, rather the device is formed from the device containing the polymer and therapeutic agent. Further, applicants specifically specify that the

annular polymer support of the sewing ring is so formed with the therapeutic agent. No where in Helmus or Tweeden is their a teaching or motivation to combine the suggested references to arrive at applicant's invention.

Because the teaching of Helmus in view of Tweden fail to provide all the necessary teachings, applicants respectfully request the present rejection be removed in view of the submitted amendments and arguments.

4. Rejection of Claims 11 and 75 under 35 U.S.C. § 103 over Helmus in view of Fearnot.

4. Claims 11 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Fearnot et al., 5,609,629.

Helmus discloses the invention substantially as claimed, see above. More specifically, Helmus discloses that the therapeutic agent comprises an anti-inflammatory agent, see column 2, line 6. Helmus also discloses that devices that could be coated with the therapeutic agents include vascular stents, see column 9, line 63. However, Helmus does not disclose the anti-inflammatory agent as being dexamethasone.

Fearnot teaches that a layer of dexamethasone coated on an implantable medical device for implantation into, for example, the vascular system, see column 4, line 33. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone onto an implantable medical device for the vascular system, as taught by Fearnot, using the methods taught by Helmus.

Claims 11 and 75 were rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Fearnot et al. 5,609,629.

As previously discussed Helmus does not provide any teaching of initially forming the annular support from a polymer mixed with the therapeutic reagent. Further, these references do not teach the by construction of the device in this manner. Further the therapeutic agent is released from the polymer to provide distal protection to the fabric overlayer. As the Examiner states, Helmus only provides a teaching for coating the structures. Adding the specific teachings of Fearnont to add dexamethasone does not provide the necessary teachings any more than Helmus or Tweeden. Consistent with the teaching of Helmus, Fearnot teaches that you can impregnate a polymer with dexathasone to provide protection of the surface of the device. Using the teachings of Helmus in view of Fearnot would teach away from initially forming the annular support with the therapeutic agent such that it can protect a second component of the device, such as the fabric overlay. The

teachings of Helmus, Tweeden and Fearnot would teach one skilled in the art to provide a coating for each component of the device.

Because the teachings of Helmus in view of Fearnot fail to provide all the necessary teachings, applicants respectfully request the present rejections to Claims 11 and 75 be removed in view of the submitted amendments and arguments.

5. Rejection of Claims 23, 27, 40, 43, 51, 54, 58, and 60 under 35 USC 103(a) Helmus et al in view of Tweden et al. in further view of Fearnot.

5. Claims 23, 27, 33, 40, 43, 51, 54, 58 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al 5,895,419, and further in view of Fearnot et al., 5,609,629.

Helmus-in-view-of-Tweden disclose the invention substantially as claimed, see above. More specifically, Helmus discloses that the therapeutic agent comprises an anti-inflammatory agent, see column 2, line 6. Helmus also discloses that devices that could be coated with the therapeutic agents include vascular stents, see column 9, line 63. However, Helmus does not disclose the anti-inflammatory agent as being dexamethasone.

Fearnot teaches that a layer of dexamethasone coated on an implantable medical device for implantation into, for example, the vascular system, see column 4, line 33. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone, as taught by Fearnot, onto implantable medical devices as taught by Helmus-in-view-of-Tweden.

Claims 23, 27, 40, 43, 51, 54, 58, and 60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden, 5,895,419, and in further view of Fearnot et al. 5,609,629.

As previously discussed Helmus only provides a teaching for protecting the device using coatings. Adding the specific teachings of Tweden and Fearnot together does not provide the necessary teachings any more than 1) Helmus in view of Tweden or 2) Helmus in view of Fearnot. Consistent with the teaching of Helmus, all the secondary references teach one skilled in the art to provide protection of the surface of the component requiring protection.

Applicants have amended their claims to clearly claim that the annular support is made from a polymer formed from the polymer mixed at the time of formation with a therapeutic drug. It does not have the drug by a coating applied to the body of the device. Similarly, the references does not teach to make the annular

support a polymer initially formed with the therapeutic agent. All references teach one skilled in the art to protect each component by adding a protective coating.

Because the teachings of Helmus in view of Teweden and Fearnot, they fail to provide all the necessary teachings, applicants respectfully request the present rejections to Claims 23, 27, 40, 43, 51, 54, 58, and 60 be removed in view of the submitted amendments and arguments.

6. Rejection of Claim 13 under 35 USC 103(a).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Chanda et al., 5,645,567.

Helmus discloses the invention substantially as claimed, see above. Additionally, Helmus discloses that the therapeutic agents may include anticalcifying drugs to prevent calcification of biomedical materials such as used in heart valves or artificial heart, see column 6, line 68 – column 7, line 3. However, Helmus does not disclose the agent being gentamicin or rifampicin.

Chanda teaches that heparin after neutralization with gentamicin is essential in prevention of calcification in tissue grafts, which is the main cause of failure of bioprosthetic heart valves, see column 3, lines 45-47, and lines 61-62. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a gentamicin in combination with heparin on the Helmus heart valve in order to prevent calcification.

Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Chanda et al. 5,645,587.

As the Examiner states, Helmus only provides a teaching for protecting the coated structures. Chanda is used to teach that anti-calcification agents, such as heparin after neutralization with gentamicin, can be used to protect the device.

Chanda teaches a chemical treatment process whereby after cross-linking you can treat the heart valve tissue with heparin and antibiotic. Chanda does not teach a polymer release system, particularly to form the annular support from a polymer and drug, and thus does not have any nexus to the other references. Treating tissue with chemicals as a process step, does not provide enough nexus to Helmus to be combined with Helmus.

Because the teachings of Helmus in view of Chanda fail to provide all the necessary teachings, applicants respectfully request the present rejections to Claim 13 be removed in view of the submitted amendments and arguments.

7. Rejection of Claim 31 under 35 USC 103(a) over Helmus et al in view of Tweden et al.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,885,419, as applied to claim 30 above, and further in view of Myers, 5,716,397.

Helmus-in-view-of-Tweden disclose the invention substantially as claimed, see above. Also, Tweden discloses an annuloplasty ring (22). However, Helmus-in-view-of-Tweden does not disclose a polymer insert comprising radiopaque flexible silicone rubber.

Myers discloses an annuloplasty ring consisting of a soft core of silicone rubber impregnated with radiopaque salt. It would have been obvious to one of ordinary skill in the art to provide radiopaque silicone rubber in the Helmus-in-view-of-Tweden polymer insert, as a known material used in forming an annuloplasty ring.

Claims 31 was rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Fearnot et al. 5,609,629, and in further view of Myers, 5,716.397.

As previously discussed Helmus and Tweden do not provide any teaching of having an annular polymer support initially formed with a therapeutic agent. Helmus and Tweden also do not to provide distal protection to a second component of the device. Adding the specific teachings of Myers to provide the Annuloplasty ring with silicone rubber impregnated with a Radiopaque salt does not over come the original problems of combining Helmus and Tweden in that the impregnated ring on provides an eluting surface, and not forming the device from a polymer mixed with the therapeutic agent.

Because the teachings of Helmus in view of Tweden fail to provide all the necessary teachings, the addition of Myers does not solve that problem. Applicants respectfully request the present rejection be removed to Claim 31 in view of the submitted amendments and arguments.

Respectfully submitted,

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AMENDED CLAIMS

Version with Markings To Show Changes Made

1. (canceled) An implantable medical device comprising a body portion overlaid by a fabric overlayer, the body portion comprising at least one polymer [intimately] mixed with at least one therapeutic agent, wherein the therapeutic agent is capable of being released from the body portion of the device and eluting through the fabric overlay to provide at least one therapeutic effect of the therapeutic agent.

2. (canceled) The implantable medical device of claim 1, wherein the constituent material comprises at least one material selected from the group consisting of a polymer, a metal, a metal alloy, a body tissue, collagen, and a biosynthetic material.

3. (canceled) The implantable medical device of claim 2, wherein the constituent material comprises a polymer selected from the group consisting of silicon, polyamide, polyimide, polycarbonate, polyether, polyester, a polyvinyl aromatic compound, polytetrafluoroethylene, poly(ethylene-chloro-trifluoroethylene), poly(ethylene-tetrafluoroethylene), poly(chloro-trifluoroethylene), a fluorinated ethylene-propylene copolymer, a perfluoroalkoxy copolymer, a fluoroelastomer, polyolefin, an ethylene-alpha olefin copolymer, an acrylic polymer, an acrylic copolymer, a vinyl halide polymer, a vinyl halide copolymer, a polyvinyl ether, a polyvinyl ester, a polyvinyl ketone, a polyvinylidine halide, polyacrylonitrile, a vinyl monomers homocopolymer, a vinyl monomer olefin copolymer, an acrylonitrile-styrene copolymer, an ABS resin, polysulfone, polyetherimide, polyetheretherketone, polyarylketone, epoxy resin, liquid crystalline polymer, polyphenylene sulfide, polyphenylene oxide, polyamideimide, polyacetal, polyketone, polyarylate, an ethylene-vinyl acetate copolymer, and blends of the aforementioned polymers.

4. (canceled) The implantable medical device of claim 3, wherein the polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

5. (canceled) The implantable medical device of claim 1, wherein the fabric overlayer comprises a knitted or woven fabric of polymer fibers.

6. (canceled) The implantable medical device of claim 5, wherein the polymer fibers are selected from the group consisting of polyester, polyamide, polyurethane, polypropylene, polyethyleneteraphthalate, poly(tetrafluoroethylene), polyethylene, poly(vinyl alcohol), polyacrylonitrile, poly(glycolic acid), poly(lactic acid), polydimethylsiloxane, aramid, and regenerated cellulose.

7. (canceled) The implantable medical device of claim 5, wherein the polymer fibers comprise polyester.

8. (canceled) The implantable medical device of claim 5, wherein the polymer fibers comprise polyethyleneteraphthalate.

9. (canceled) The implantable medical device of claim 1, wherein the therapeutic agent comprises an anti-inflammatory agent.

10. (canceled) The implantable medical device of claim 9, wherein the anti-inflammatory agent is selected from the group consisting of cortisol, cortisone, fludrocortisone, prednisone, prednisolone, 6α-methylprednisolone, triamcinolone, betamethasone, dexamethasone, beclomethasone, aclomethasone, amcinonide, clebethasol, clocortolone, gold thiomalate, gold thiosulfate, auranofin, D-penicilamine, rofecoxib, celecoxib, derivatives thereof, and salts thereof.

11. (canceled) The implantable medical device of claim 10, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

12. canceled) The implantable medical device of claim 9, wherein the therapeutic agent further comprises an antimicrobial agent.

13. (canceled) The implantable medical device of claim 12, wherein the antimicrobial agent comprises at least one of rifampicin and gentamicin.

14. (canceled) The implantable medical device of claim 1, wherein the therapeutic agent is coated onto the body portion of the device.

15. (canceled) The implantable medical device of claim 1, wherein the therapeutic agent is compounded into the body portion of the device.

16. (canceled) The implantable medical device of claim 1, wherein the body portion of the device comprises a liquid core comprising the therapeutic agent.

17. (canceled) The implantable medical device of claim 1, wherein the therapeutic agent comprises an antimicrobial agent.

18. (canceled) The implantable medical device of claim 1, selected from the group consisting of a prosthetic heart valve, an annuloplasty ring, a vascular graft, a sewing ring, a stent, a medical electrical lead, an indwelling catheter, a pacemaker and a drug infusion pump.

19. (canceled) The implantable medical device of claim 18, selected from the group consisting of a prosthetic heart valve, an annuloplasty ring, a vascular graft, and a sewing ring.

20. (canceled) The implantable medical device of claim 1, wherein the fabric overlayer takes the form of a sheath, pouch, an encasement, an enclosure, a layer, a film, or a coating.

21. (currently amended) A heart valve prosthesis comprising à sewing ring comprising an annular support initially formed from [a body portion comprising] a biostable polymer [intimately] mixed with a therapeutic agent, said annular support [body portion] overlayed by a polyester fabric overlayer, wherein said annular support [body portion] provides at least one therapeutic effect to the fabric overlayer.

.

22. (original) The heart valve prosthesis of claim 21, wherein the biostable polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

23. (original) The heart valve prosthesis of claim 21, wherein the therapeutic agent comprises an anti-inflammatory agent selected from the group consisting of dexamethasone, a derivative thereof, or a salt thereof.

24. (original) The heart valve prosthesis of claim 21, which is a bioprosthetic heart valve.

25. (currently amended) A heart valve prosthesis comprising a sewing ring comprising a body portion initially formed from [comprising] a polymer [intimately] mixed with a therapeutic agent, said body portion overlayed by a polyester fabric overlayer, and wherein said body portion provides at least one therapeutic effect to the fabric overlayer.

26. (currently amended) The heart valve prosthesis of claim 25, wherein the heart valve prosthesis additionally comprises metal or metal alloy components [comprises at least one titanium and tantalum].

27. (original) The heart valve prosthesis of claim 25, wherein the therapeutic agent comprises and anti-inflammatory agent selected from the group consisting of dexamethasone, a derivative thereof, or a salt thereof.

28. (original) The heart valve prosthesis of claim 21, which is a mechanical heart valve.

29. (currently amended) [In a]A bioprosthetic heart valve comprising a polymer insert containing struts attached to tissue leaflets to form a valve housing, wherein a fabric sheath encloses the polymer insert to form a sewing ring, said sewing ring attached circumferentially to the base of the valve housing, the improvement comprising [an]the polymer insert is initially formed with a releasable therapeutic agent [polymer intimately mixed in intimate contact with the polymer insert] wherein the releasable therapeutic agent provides at least one therapeutic effect to the fabric overlayer.

30. (original) The bioprosthetic heart valve of claim 29, wherein the polymer insert comprises silicone.

31. (currently amended) The bioprosthetic heart valve of claim 30, wherein the polymer insert comprises radiopaque flexible silicone rubber and a therapeutic agent.

32. (original) The bioprosthetic heart valve of claim 29, wherein the therapeutic agent comprises an anti-inflammatory agent.

33. (original) The bioprosthetic heart valve of claim 32, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

34. (original) The bioprosthetic heart valve of claim 29, wherein the therapeutic agent comprises an antimicrobial agent.

35. (original) The bioprosthetic heart valve of claim 29, wherein the flow occluder comprises pericardium or aortic root tissue from an animal.

36. (original) The bioprosthetic heart valve of claim 35, wherein the flow occluder comprises pericardium or aortic root tissue from a pig.

37. (cancelled) In a mechanical heart valve comprising a metallic ringed valve housing containing a central metallic strut along which a flow occluder disk moves, wherein a fabric sheath encloses a metal insert to form a sewing ring, the improvement comprising a releasable therapeutic agent [intimately] initially mixed with at least one polymer added to the sewing ring wherein the releasable therapeutic agent provides at least one therapeutic effect to at least one additional component of the heart valve.

38. (canceled) The mechanical heart valve of claim 37, wherein the metal insert comprises at least one of titanium and a titanium alloy.

39. (canceled) The mechanical heart valve of claim 37, wherein the therapeutic agent comprises an anti-inflammatory agent.

40. (canceled) The mechanical heart valve of claim 39, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

41. (currently amended) An annuloplasty ring comprising a body portion overlaid by a polyester fabric overlayer, the body portion [comprising]initially formed from a biostable polymer [intimately] mixed with an releasable therapeutic agent wherein the releasable therapeutic agent provides at least one therapeutic effect to the fabric overlayer.

42. (original) The annuloplasty ring of claim 40, wherein the biostable polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

43. (original) The annuloplasty ring of claim 40, wherein the therapeutic agent comprises an anti-inflammatory agent selected from the group consisting of dexamethasone, a derivative thereof, or a salt thereof.

44. (original) The annuloplasty ring of claim 40, wherein the therapeutic agent comprises an antimicrobial agent.

45. (currently amended) A method for replacing a heart valve in a patient comprising implanting a prosthetic heart valve into the patient, wherein the prosthetic heart valve comprises a sewing ring comprising a body portion [comprising a constituent material in intimate contact] initially formed from a polymer mixed with a therapeutic agent, said body portion additionally overlayed by a fabric overlayer.

46. (original) The method of claim 45, wherein the constituent material of the body portion comprises a biostable polymer.

47. (original) The method of claim 46, wherein the biostable polymer comprises a polymer selected from the group consisting of polyurethanes, silicones and combinations thereof.

48. (currently amended) The method of claim 45, wherein the constituent material of the body portion additionally comprises a metal or a metal alloy.

49. (original) The method of claim 46, wherein the metal or metal alloy comprises titanium.

50. (original) The method of claim 45, wherein the therapeutic agent comprises an anti-inflammatory agent.

51. (original) The method of claim 50, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

52. (currently amended) A method for ameliorating the inflammatory response associated with heart valve replacement in a patient comprising implanting a prosthetic heart valve into the patient, wherein the prosthetic heart valve comprises a sewing ring comprising a body portion comprising a polymer [intimately mixed] initially formed with a releasable anti-inflammatory agent, said body portion overlayed by a fabric overlayer wherein the releasable therapeutic agent provides at least one therapeutic effect to at least one additional component of the heart valve.

53. (original) The method of claim 52, wherein the fabric overlayer comprises polyester.

54. (original) The method of claim 52, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

55. (original) The method of claim 52, wherein implantation of the prosthetic heart valve is accompanied by reduced pannus formation at the implant site.

56. (currently amended) A method for ameliorating the inflammatory response associated with heart valve repair in a patient comprising implanting an annuloplasty ring into the patient, wherein the annuloplasty ring comprises a body portion comprising [an]a biostable polymer initially formed [mixed] with a releasable anti-inflammatory agent, said body portion overlaid by a fabric overlayer wherein the releasable therapeutic agent provides at least one therapeutic effect to the fabric overlayer.

57. (original) The method of claim 56, wherein the fabric overlayer comprises polyester.

58. (original) The method of claim 56, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

59. (original) The method of claim 56, wherein implantation of the annuloplasty ring is accompanied by reduced pannus formation at the implant site.

60. (currently amended) A method of making a medical sewing ring comprising:

initially forming the annular insert by mixing a releasable therapeutic agent with a biocompatible polymer; and[incorporating a therapeutic agent into an annular insert comprising a constituent material, such that the therapeutic agent is mixed with the constituent material;]

enclosing the annular insert in a fabric sheath;

wherein the releasable therapeutic agent provides at least one therapeutic effect to the fabric sheath.

61. (original) The method of claim 60, wherein the constituent material comprises a polymer.

62. (original) The method of claim 61, wherein the constituent material comprises a biostable polymer.

63. (original) The method of claim 62, wherein the biostable polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

64. (original) The method of claim 60, wherein the constituent material comprises a metal or a metal alloy.

65. (original) The method of claim 64, wherein the metal or metal alloy is selected from the group consisting of titanium, tantalum, titanium alloys, cobalt chrome alloys, nickel chrome alloys, stainless steels, and combinations thereof.

66. (original) The method of claim 60, wherein the fabric sheath comprises polyester.

67. (original) The method of claim 60, wherein the therapeutic agent comprises an anti-inflammatory agent.

68. (original) The method of claim 67, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

69. (original) The method of claim 60, wherein the therapeutic agent comprises an antimicrobial agent.

70. (original) The method of claim 67, wherein the therapeutic agent further comprises an antimicrobial agent.

71. (canceled) The method of claim 60, wherein incorporating a therapeutic agent into an annular insert comprises compounding the therapeutic agent into the annular insert.

72. (canceled) The method of claim 60, wherein incorporating a therapeutic agent into an annular insert comprises coating the therapeutic agent onto the annular insert.

73. (canceled) An implantable infusion pump comprising:

a pump comprising an interior space for containment of a liquid;

a delivery catheter for delivery of the liquid to a patient; and

a polyester pouch surrounding the pump;

said pump further comprising a constituent material in intimate contact with an anti-inflammatory agent, said anti-inflammatory agent capable of being released from the pump and eluting through the polyester pouch.

74. (canceled) The implantable infusion pump of claim 73, wherein the anti-inflammatory agent is coated or adhered to the surface of the pump.

75. (canceled) The implantable infusion pump of claim 74, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.